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THE EXPERTS IN STANDING

K083017

510(k) Summary of Safety and Effectiveness

Submitter: LEVO AG
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OCT 24 2008

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Contact Person: Mr. Thomas Nietlisbach, Construction Engineer
Mr. Thomas Raeber, CEO

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Device Name: **LEVO** *C*^{3}

Classification Name: Electrical Power Wheelchair, Stand-up

Identification of Predicate Devices:
LEVO *combi* (K 030893)
LEVO *comfort II* (K 051387)
Permobil C350 PS (K 071650)

Intended Use: The **LEVO** *C*^{3} power wheelchair is a product which changes people's position in/from seating or/to standing but also any position in between. The product provides high indoor and outdoor mobility on surfaces like tar, grass and gravel. However, it is not allowed to drive in standing position on uneven ground.

Device Description: The **LEVO** *C*^{3} with optional seating and standing position function is center wheel driven, battery powered, motor driven power wheelchair and is controlled by the PG Drives Technology's power wheelchair controller "VR2". The joystick is integrated in the controller. The wheelchair is powered by two 12V/55Ah or two 12V/72Ah batteries with a theoretical driving range of 25km (55Ah), 35km (72Ah).

The **LEVO** C^3 power wheelchair is a product which changes people's position in/from seating or/to standing but also any position in between.

The electrical positioning change is integrated in an electrical center wheel drive power wheelchair that performs high indoor and outdoor mobility in any optional possible position. For security, the speed is reduced to half speed as soon as the patient is not in the sitting position.
Components: The **LEVO** C^3 power wheelchair consists of three basic sub-sections. These are the base with drive units, the PG Drives Technology's VR2-Control System, and the body supporting system including the mechanisms with actuators to change positions.

The base of the **LEVO** C^3 includes the frame, four direct-drive units with integrated parking brakes, two 12V/55Ah or two 12V/72Ah batteries, two 2.80/2.50-4" straight front and two 3.00-8" center driving wheels as well as two 7X1¾" twin rear castor wheels. The base also includes a vehicle tie-down kit.

PG Drives Technology's VR2-Control System includes the power module, the integrated actuator module and the controller with integrated joystick.

The body supporting system includes the seat support, the back support, armrests and leg rests and the mechanisms with actuators to change positions. This optional position change mechanism allows people to switch into/from seating or/to standing but also any position in between including tilt in space. The whole body support system is equipped with the latest low shearing design to prevent shearing forces or dislocations during changing positions.

Safety and Effectiveness: The **LEVO** C^3 was developed on experience of the **LEVO** *combi*, **LEVO** *comfort II* and all other powered wheelchairs previously developed and produced by LEVO AG since 1975. Experience from the past has shown that the centre wheel driven power wheel chair has the most compact and efficient manoeuvrability capability with some limitations when it comes up to obstacles and steep ramps. A front wheel driven power chair offers this best capability while the user is in standing. The new power wheelchair **LEVO** C^3 has been developed as a combination of both and uses in regards of the power motors as well as the controller the same technology as already used and proved in the market. The seating and positioning components are also built up based on experience and became special focus on known stressed components. The whole new power chair with its inbuilt new technologies for improvements in effectiveness and safeties, in many regards shows similarities to the above mentioned products, but also has

been tested after the latest ISO, EN and ANSI/RESNA standards as listed in this documentation.

So the **LEVO** C^3 has in substantial the same technological characteristics and the same safety and effectiveness as the predicate device(s) and the minor changes declared in the Submission do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LEVO AG
% TÜV SÜD America, Inc.
Mr. Stefan Preiss
1775 Old Highway 8 / Suite 104
New Brighton, Minnesota 55112-1891

OCT 24 2008

Re: K083017
Trade/Device Name: LEVO C^3 Standup Wheelchair
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair.
Regulatory Class: Class II
Product Code: IPL
Dated: October 7, 2008
Received: October 9, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number: not known

Proprietary Name
of the new Device: **LEVO** C^3

Indications for Use: The **LEVO** C^3 power wheelchair with optional seating and standing position function may be of interest for any individuals who needs a power wheelchair and cannot stand up on their own such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc..

Intended use: The **LEVO** C^3 power wheelchair is a product which changes people's position in/from seating or/to standing but also any position in between. The product provides high indoor and outdoor mobility.

Prescription Use (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **XX** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083017